

**K102771 BIOPSY HANDY, MRI BIOPSY HANDY**Jun 24, 2011  
273 days to decisionK102771 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k102771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 24, 2010
Decision date	Jun 24, 2011
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somatex Medical Technologies GmbH</b>
Location	Cambridge, MA, US
Contact	SUSANNE RAAB
510(k) history	7 submissions · 7 cleared · 2008-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102771/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026